Clinical Research Subject Screening Process

Approval signature: Michael Bookman, M.D., Director of CRSS

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Purpose:
To standardize the process of screening human subjects for clinical research studies at the University of Arizona Cancer Center (UACC).

References:
- All SOPs are applicable to this SOP.

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
Personnel who screen subjects for clinical research studies at the UACC.

Tools:
- Clinic Packet
- UACC Research Patient Questionnaire
- OnCore
- Form FDA 1572
- Example Subject Screening Summary #1 (Attachment 1)
- Example Subject Screening Summary #2 (Attachment 2)
- Pharmacy Registration Form (Attachment 3)
- NCI booklet: Taking Part in Cancer Treatment Research Studies
Definition of Terms:

- **UACC Research Patient Questionnaire**: Medical history form.
- **Clinical Research Team Member**: Principal Investigator, Co-Principal Investigator, Sub-Investigators, Research Nurses and Clinical Research Coordinators designated by the Principal Investigator to participate in the conduct of the clinical trial on the delegation of authority log.
- **Clinic Packet**: A packet that contains the subject's consent form, any other study specific consents (tissue consent, biomarker research, etc), consent verification page, subject's authorization form for use and disclosure of protected health information (PHI) for research (if applicable for study), Fast Facts and/or equivalent, study schema/flowsheet, pre-authorization form and NCI booklet *Taking Part in Cancer Treatment Research Studies* in English (Spanish NCI booklet also available), as well as any other pertinent study related materials.
- **Consenter/Presenter**: An individual delegated by the Principal Investigator (PI) who may explain the basic elements (study design, required procedures, risks, etc.) of the clinical research study to the patient. This individual may sign as “consenter” or “presenter” on the informed consent document.
- **Co-Principal investigator (Co-PI)**: Assists the PI with the conduct of the clinical study. He/she oversees all aspects from IRB submissions to patient care. May sign as the investigator consenter/presenter (depending on consent terminology) on the informed consent document.
- **CRC**: Clinical Research Coordinator.
- **MRN**: Medical Record Number.
- **OnCore**: Electronic Data Capture System used to access the electronic database that stores study protocol and subject data at the University of Arizona Cancer Center.
- **Principal Investigator (PI)**: The individual who is ultimately responsible for the conduct of the clinical trial. He/she oversees all aspects from IRB submissions to patient care. Signs as the investigator on the informed consent document.
- **Sub-Investigator**: Any individual member of the clinical trial team designated on the FDA Form 1572 and supervised by the Principal Investigator at the trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g.; associates, residents, research fellows, nurse practitioners) and are included on the form FDA 1572. May sign as the investigator or consenter/presenter (depending on consent terminology) on the informed consent document.
- **Verification of Training Form (VOTF)**: Verification of all individuals conducting research involving human subjects (with or without financial support of any sponsoring organization or agency) who have completed Human Subjects training (CITI).

Safety Issues:
Patients will be fully informed of risks and benefits of participating in a clinical research study. Study related procedures will not be initiated until a fully executed informed consent form is obtained, however, review of the patient's medical history may commence. Screening can start/continue while financial approval is obtained.
Process Steps:
1) Physician selects a clinical research study and obtains the clinic packet for that study.
2) Physician reviews the inclusion/exclusion checklist to see if the subject initially meets study criteria.
3) Physician contacts the Research Nurse and/or the CRC to notify them that a potential study subject has been identified and the Physician will initiate the informed consent discussion with the patient, if the patient is amenable. The Research Nurse and/or CRC may be present for the informed consent discussion.
4) Physician reviews and performs the initial discussion of the informed consent with the study subject.
5) If subject is interested in participating in the study, an informed consent will be provided. After reading the informed consent form, and all questions have been answered, the subject must complete all appropriate pages, initial each page if applicable, and sign and date, with the time if applicable.
6) A member of the clinical research team (PI, Co-PI, Sub-I, Research Nurse, Clinical Research Coordinator) places a patient label (with the patient’s name, MRN and date of birth) on every page of signed consent document.
7) Clinical research team member verifies that the subject has completed the appropriate pages, signs, and dates the consent form. The physician or his/her designee who conducted the informed consent discussion signs and dates, with the time if applicable, as the consenter/presenter of the study on the appropriate pages of the informed consent document(s). The PI/Co-PI or Sub-Investigator will sign the informed consent document as the investigator, if applicable. If applicable, the PI, Co-PI or Sub-I signs the original informed consent document as the investigator within the protocol specified window or 14 days if not specified by the protocol, otherwise, this will fall to a designated Clinical Research Team Member within the protocol specified or 14 day window. Clinical research team member provides and reviews the NCI booklet with the subject. Research Nurse will further review the NCI booklet with the subject.
8) Clinical research team member completes the consent verification page. A research team member documents the consent process on this page as to those present, questions asked, and answers given. The original consent verification page is attached to the original informed consent document, which is kept on file at the UACC North Campus in room 2111. One copy is attached to the informed consent document in the research chart.
9) Note: A new consent verification page must be completed each time consent is obtained.
10) If applicable, Research Nurse or CRC meets with the subject after informed consent is obtained by the physician.
11) Research Nurse or CRC confirms that the consent is fully executed and that the consent form date is most current version.
12) If applicable, the Research Nurse or CRC obtains HIPAA consent from subject.
13) Research Nurse or CRC makes copies of the fully executed consent form and HIPAA form for incorporation into the subject’s medical record and research chart, and provides subject with a copy.

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14) Informed consent and PHI authorization form obtained. Registration, randomization and treatment cannot be completed until fully executed consent is obtained. Research Nurse or CRC completes the pre-authorization form and provides it to the applicable Financial Office Representative.

15) Research Nurse reviews and completes as much of the Research Patient Questionnaire as time allows.

16) Research Nurse or CRC provides contact information to the subject and addresses any study-related questions.

17) Research Nurse or CRC retrieves pre-authorization form from the financial office when completed and approved. If there are any delays in the financial approval process, the Clinical Trials Budget/Financial staff will be notified immediately to assist in facilitating approval. The physician will be notified if this will cause a delay in scheduling and/or treatment.

18) Research Nurse writes or obtains orders for study-related procedures to be used once pre-authorization is obtained and proceeds with the scheduling study process.

19) Research team member delivers exit form/orders to Scheduler and remaining consents, inclusion/exclusion checklist and study schedule to the CRC who reviews the study schedule for completeness.

20) Research Nurse (or CRC for SWOG/GOG trials) determines anticipated first treatment date and relays information to the subject, CRC and Physician.

21) CRC ensures that the treating physician is listed on the Form FDA 1572 and VOTF.

22) CRC obtains medical records and proceeds with screening review.

23) CRC enters subject in the OnCore database as a candidate.

25) A research chart will be made and shared by clinical research team (if applicable).

26) CRC reviews the study schedule to make sure that it is complete and to ensure that all tests are done and the subject still meets eligibility criteria.

27) CRC completes the Subject Screening Summary (Examples 1 and 2) and eligibility checklist. (see Examples 1 and 2) CRCs will obtain QA/QC verification from a fellow CRC.

28) Confirmation of subject eligibility is reviewed by the Research Nurse, CRC, treating physician and PI after all screening results are obtained. PI, Research Nurse and CRC sign off on inclusion/exclusion checklist that subject remains eligible.

29) If subject is confirmed to be eligible, he/she will be registered, randomized, enrolled with the sponsor and updated in OnCore by the CRC. Once registered, the CRC completes the Pharmacy Registration form (Attachment 1). The original registration form will be delivered to the research pharmacist or their designee per pharmacy instruction. A copy of the Pharmacy Registration form will be filed in the patient’s research chart.

If the subject is a screen failure, the original consent form and HIPAA consent form along with the original consent verification page, will be filed in UACC North room 2111. The consent verification page must include an explanation of why the subject failed screening. A copy of the signed consent form(s) and a copy of the consent verification page will be placed in the subject’s screen failure chart. Copies will not be placed in the subject’s medical record.

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Note: All calls to and from study subjects are routed through the Research Nurse if they pertain to medical issues (toxicities, drug questions, etc.). Otherwise, calls regarding study appointments, treatment schedules, etc. may be routed through the CRC.
Attachment 1
Example Subject Screening Summary #1

<table>
<thead>
<tr>
<th>Name:</th>
<th>ID #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Drug:</td>
<td>MRN #:</td>
</tr>
<tr>
<td>Protocol #:</td>
<td>Race:</td>
</tr>
<tr>
<td>Attending MD:</td>
<td>Height:</td>
</tr>
<tr>
<td>Referring MD:</td>
<td>PS:</td>
</tr>
<tr>
<td>Consent Date:</td>
<td></td>
</tr>
<tr>
<td>Target Tx Date:</td>
<td>Other/Comments:</td>
</tr>
<tr>
<td>Dose/Arm:</td>
<td></td>
</tr>
</tbody>
</table>

**PATHOLOGY**

<table>
<thead>
<tr>
<th>Date Collected:</th>
<th>Bcdy Site Biopsied:</th>
<th>Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

History, Institution & if Outside Review of Slides:
Any Other Information:
<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
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<tbody>
<tr>
<td>Surgery</td>
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<tr>
<td>Prior Therapy</td>
<td></td>
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<tr>
<td>Medical History</td>
<td></td>
</tr>
<tr>
<td>Medications</td>
<td></td>
</tr>
<tr>
<td>Baseline Signs/Symptoms</td>
<td></td>
</tr>
<tr>
<td>Allergies</td>
<td></td>
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<tr>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>Pending</td>
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Screened by: ____________________________

Date: ________________
## SUBJECT SCREENING SUMMARY #2

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<th>Name:</th>
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<tbody>
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<td>Protocol Drug:</td>
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<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Allergies:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Pre-study studies Pending:</th>
</tr>
</thead>
</table>

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Cancer History

Family (social) Hx

Medical Surgical History

(Baseline signs/symptoms) or if avail.  \( \text{Dx date (end date or cont)} \) \( \text{Tx (meds)} \)

Subject screening log ___ ___
Attachment 3

Pharmacy Registration Notification

Protocol: ________________________________

Study Title: ________________________________

Tx Assignment: ________________________________

Dose Assignment: ________________________________

Start Date: ________________________________

Patient Name: ________________________________

MRN: ________________________________

Patient Study Initials: ________________________________

Patient Study ID: ________________________________

Consent Date: ________________________________

Randomization Date: ________________________________

P.I.: Please select ________________________________

Research Nurse: Please select ________________________________

CRC: Please select ________________________________

Treating Physician: Please select ________________________________

Registration attached: □

Consent verification: Initial here to verify that the most current version of the consent form available for this protocol as of cycle 1, day 1, has been fully executed by the patient and an investigator listed on the 1572 for the protocol. ______/______

Registered by: ________________________________ Date: __________

Reviewed by: ________________________________ Date: __________

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